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4 Attorneys for Defendant
PFIZER INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

1 NOW COMES Defendant Pfizer Inc. ("Defendant"), and files this Answer to Plaintiff's
2 Complaint ("Complaint"), and would respectfully show the Court as follows:

3 **I.**

4 **PRELIMINARY STATEMENT**

5 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
6 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally.
7 Defendant may seek leave to amend this Answer when discovery reveals the specific time
8 periods in which Plaintiff was prescribed and used Celebrex®.

9 **II.**

10 **ANSWER**

11 **Response to Allegations Regarding Parties, Jurisdiction, and Venue**

12 1. Defendant is without knowledge or information sufficient to form a belief as to the truth
13 of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
14 whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant denies the
15 remaining allegations in this paragraph of the Complaint.

16 2. Defendant states that this paragraph of the Complaint contains legal contentions to
17 which no response is required. To the extent that a response is deemed required, Defendant
18 admits that it is a Delaware corporation with its principal place of business in New York.
19 Defendant admits that it is registered to do and does business in the State of Maryland.
20 Defendant denies any wrongful conduct, denies having committed a tort in the State of
21 Maryland, and denies the remaining allegations in this paragraph of the Complaint.

22 3. Plaintiff's Complaint omits paragraph number 3.

23 4. Defendant states that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendant is
25 without knowledge or information sufficient to form a belief as to the truth of the allegations in
26 this paragraph of the Complaint concerning Plaintiff's citizenship and the amount in
27 controversy, and, therefore, denies the same. However, Defendant admits that Plaintiff claims
28 that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of

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1 interests and costs. Defendant denies the remaining allegations in this paragraph of the
2 Complaint.

3 5. Defendant states that this paragraph of the Complaint contains legal contentions to
4 which no response is required. To the extent that a response is deemed required, Defendant is
5 without knowledge or information sufficient to form a belief as to the truth of the allegations in
6 this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore,
7 denies the same. Defendant admits that, during certain periods of time, it marketed and co-
8 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
9 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
10 admits that it provided FDA-approved prescribing information regarding Celebrex®.
11 Defendant admits that it does business in the State of Maryland. Defendant denies any
12 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

13 **Response to Factual Allegations**

14 6. Defendant admits that, during certain periods of time, it marketed and co-promoted
15 Celebrex® in the United States, including Maryland, to be prescribed by healthcare providers
16 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
17 Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®.
18 Defendant denies the remaining allegations in this paragraph of the Complaint.

19 7. Defendant is without knowledge or information sufficient to form a belief as to the truth
20 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
22 and effective when used in accordance with its FDA-approved prescribing information.
23 Defendant denies that Celebrex® caused Plaintiff injury or damage and denies the remaining
24 allegations in this paragraph of the Complaint.

25 8. Defendant states that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant states that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

1 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
2 of the Complaint.

3 9. Defendant admits that, during certain periods of time, it marketed and co-promoted
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
6 that it provided FDA-approved prescribing information regarding Celebrex®. Defendant
7 denies the remaining allegations in this paragraph of the Complaint.

8 10. Defendant admits that Celebrex® is in a class of drugs that is, at times, referred to as
9 non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendant states that Celebrex® is a
10 prescription medication which is approved by the FDA for the following indications: (1) for
11 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
12 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
13 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
14 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
15 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
16 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
17 and older. Defendant denies the remaining allegations in this paragraph of the Complaint.

18 11. Defendant states that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant denies any wrongful conduct and
20 denies the remaining allegations in this paragraph of the Complaint.

21 12. Defendant states that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant states that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
26 of the Complaint.

27 13. Defendant states that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®.
4 Defendant denies the remaining allegations in this paragraph of the Complaint.

5 14. Defendant states that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendant states that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
10 of the Complaint.

11 15. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury
12 or damage, and denies the remaining allegations in this paragraph of the Complaint.

13 **Response to First Cause of Action: Negligence**

14 16. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 17. Defendant admits that, during certain periods of time, it marketed and co-promoted
17 Celebrex® in the United States to be prescribed by healthcare providers who are by law
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
19 the remaining allegations in this paragraph of the Complaint.

20 18. Defendant states that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies any wrongful conduct, denies that Celebrex® is unreasonably dangerous, and
25 denies the remaining allegations in this paragraph of the Complaint.

26 19. Defendant states that this paragraph of the Complaint contains legal contentions to
27 which no response is required. To the extent that a response is deemed required, Defendant
28 admits that it had duties as are imposed by law but denies having breached such duties.

1 Defendant states that Celebrex® was and is safe and effective when used in accordance with its
2 FDA-approved prescribing information. Defendant states that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
6 damage, and denies the remaining allegations in this paragraph of the Complaint.

7 20. Defendant states that this paragraph of the Complaint contains legal contentions to
8 which no response is required. To the extent that a response is deemed required, Defendant
9 admits that it had duties as are imposed by law but denies having breached such duties.
10 Defendant states that Celebrex® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendant states that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
15 damage, and denies the remaining allegations in this paragraph of the Complaint.

16 Answering the unnumbered paragraph following Paragraph 20 of the Complaint,
17 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
18 damage, and denies the remaining allegations in this paragraph of the Complaint.

19 **Response to Second Cause of Action: Strict Products Liability**

20 21. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
21 Complaint as if fully set forth herein.

22 22. Defendant states that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendant states that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendant denies any wrongful conduct, denies that Celebrex® is defective or unreasonably
27 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

28 23. Defendant states that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendant states that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the
5 remaining allegations in this paragraph of the Complaint.

6 24. Defendant states that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the
11 remaining allegations in this paragraph of the Complaint.

12 25. Defendant is without knowledge or information sufficient to form a belief as to the truth
13 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
15 and effective when used in accordance with its FDA-approved prescribing information.
16 Defendant states that the potential effects of Celebrex® were and are adequately described in its
17 FDA-approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendant denies any wrongful conduct, denies that
19 Celebrex® is defective, and denies the remaining allegations in this paragraph of the
20 Complaint.

21 26. Defendant states that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant states that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the
26 remaining allegations in this paragraph of the Complaint.

27 27. Defendant states that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the
4 remaining allegations in this paragraph of the Complaint.

5 28. Defendant states that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendant states that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendant denies any wrongful conduct, denies that Celebrex® is defective, denies that
10 Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this
11 paragraph of the Complaint.

12 Answering the unnumbered paragraph following Paragraph 28 of the Complaint,
13 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
14 damage, and denies the remaining allegations in this paragraph of the Complaint.

15 **Response to Third Cause of Action: Fraud**

16 29. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
17 Complaint as if fully set forth herein.

18 30. Defendant is without knowledge or information sufficient to form a belief as to the truth
19 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
21 and effective when used in accordance with its FDA-approved prescribing information.
22 Defendant states that the potential effects of Celebrex® were and are adequately described in its
23 FDA-approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendant denies any wrongful conduct, denies that
25 Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this
26 paragraph of the Complaint.

27 Answering the unnumbered paragraph following Paragraph 30 of the Complaint,
28 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or

1 damage, and denies the remaining allegations in this paragraph of the Complaint.

2 **Response to Fourth Cause of Action: Negligent Misrepresentation**

3 31. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
4 Complaint as if fully set forth herein.

5 32. Defendant admits that, during certain periods of time, it marketed and co-promoted
6 Celebrex® in the United States to be prescribed by healthcare providers who are by law
7 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states
8 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
9 prescribing information. Defendant states that the potential effects of Celebrex® were and are
10 adequately described in its FDA-approved prescribing information, which was at all times
11 adequate and comported with applicable standards of care and law. Defendant denies any
12 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

13 33. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
14 Complaint as if fully set forth herein. Defendant is without knowledge or information sufficient
15 to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding
16 whether Plaintiff used Celebrex®, and, therefore, denies the same. Defendant states that
17 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
18 prescribing information. Defendant states that the potential effects of Celebrex® were and are
19 adequately described in its FDA-approved prescribing information, which was at all times
20 adequate and comported with applicable standards of care and law. Defendant denies any
21 wrongful conduct, denies that Celebrex® is defective, denies that Celebrex® caused Plaintiff
22 injury or damage, and denies the remaining allegations in this paragraph of the Complaint,
23 including all subparts.

24 34. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury
25 or damage, and denies the remaining allegations in this paragraph of the Complaint.

26 Answering the unnumbered paragraph following Paragraph 34 of the Complaint,
27 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
28 damage, and denies the remaining allegations in this paragraph of the Complaint.

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Response to Fifth Cause of Action: Express Warranty for Goods

2 35. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
3 Complaint as if fully set forth herein.

4 36. Defendant states that this paragraph of the Complaint contains legal contentions to
5 which no response is required. To the extent that a response is deemed required, Defendant
6 admits that it had duties as are imposed by law but denies having breached such duties.
7 Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex®
8 in the United States to be prescribed by healthcare providers who are by law authorized to
9 prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex®
10 was and is safe and effective when used in accordance with its FDA-approved prescribing
11 information. Defendant states that the potential effects of Celebrex® were and are adequately
12 described in its FDA-approved prescribing information, which was at all times adequate and
13 comported with applicable standards of care and law. Defendant denies any wrongful conduct,
14 denies that Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations
15 in this paragraph of the Complaint.

16 Answering the unnumbered paragraph following Paragraph 36 of the Complaint,
17 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
18 damage, and denies the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Implied Warranty

A. Warranty of Merchantability

21 37. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
22 Complaint as if fully set forth herein.

38. Defendant is without knowledge or information sufficient to form a belief as to the truth
of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
Celebrex®, and, therefore, denies the same. Defendant admits that, during certain periods of
time, it marketed and co-promoted Celebrex® in the United States to be prescribed by
healthcare providers who are by law authorized to prescribe drugs in accordance with their
approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used

1 in accordance with its FDA-approved prescribing information. Defendant states that the
2 potential effects of Celebrex® were and are adequately described in its FDA-approved
3 prescribing information, which was at all times adequate and comported with applicable
4 standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is
5 defective, and denies the remaining allegations in this paragraph of the Complaint.

6 39. Defendant states that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct, denies that Celebrex® is defective, denies that
11 Celebrex® caused Plaintiff injury or damage, and denies the remaining allegations in this
12 paragraph of the Complaint.

13 **B. Warranty of Fitness**

14 40. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 41. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, denies the same. Defendant admits that, during certain periods of
19 time, it marketed and co-promoted Celebrex® in the United States to be prescribed by
20 healthcare providers who are by law authorized to prescribe drugs in accordance with their
21 approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used
22 in accordance with its FDA-approved prescribing information. Defendant states that the
23 potential effects of Celebrex® were and are adequately described in its FDA-approved
24 prescribing information, which was at all times adequate and comported with applicable
25 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
26 allegations in this paragraph of the Complaint.

27 42. Defendant states that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
4 damage, and denies the remaining allegations in this paragraph of the Complaint.

5 Answering the unnumbered paragraph following Paragraph 42 of the Complaint,
6 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
7 damage, and denies the remaining allegations in this paragraph of the Complaint.

8 **Response to Seventh Cause of Action: Unjust Enrichment**

9 43. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
10 Complaint as if fully set forth herein.

11 44. Defendant is without knowledge or information sufficient to form a belief as to the truth
12 of the allegations in this paragraph of the Complaint, and, therefore, denies the same.
13 Defendant denies the remaining allegations in this paragraph of the Complaint.

14 45. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
17 and effective when used in accordance with its FDA-approved prescribing information.
18 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
19 of the Complaint.

20 46. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, denies the same. Defendant states that Celebrex® was and is safe
23 and effective when used in accordance with its FDA-approved prescribing information.
24 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
25 of the Complaint.

26 Answering the unnumbered paragraph following Paragraph 46 of the Complaint,
27 Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiff injury or
28 damage, and denies the remaining allegations in this paragraph of the Complaint.

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III.

GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

1 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

2 **Sixth Defense**

3 6. Plaintiff's action is barred by the statute of repose.

4 **Seventh Defense**

5 7. Plaintiff's claims against Defendant are barred to the extent Plaintiff was contributorily
6 negligent, actively negligent or otherwise failed to mitigate Plaintiff's damages, and any
7 recovery by Plaintiff should be diminished accordingly.

8 **Eighth Defense**

9 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
10 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part
11 of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in
12 any way.

13 **Ninth Defense**

14 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
15 intervening causes for which Defendant cannot be liable.

16 **Tenth Defense**

17 10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were
18 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
19 of God.

20 **Eleventh Defense**

21 11. Defendant affirmatively denies that it violated any duty owed to Plaintiff.

22 **Twelfth Defense**

23 12. A manufacturer has no duty to warn patients or the general public of any risk,
24 contraindication, or adverse effect associated with the use of a prescription medical product.
25 Rather, the law requires that all such warnings and appropriate information be given to the
26 prescribing physician and the medical profession, which act as a "learned intermediary" in
27 determining the use of the product. Celebrex® is a prescription medical product, available only
28 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's

1 treating and prescribing physicians.

2 **Thirteenth Defense**

3 13. The product at issue was not in a defective condition or unreasonably dangerous at the
4 time it left the control of the manufacturer or seller.

5 **Fourteenth Defense**

6 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit
7 for its intended use and the warnings and instructions accompanying Celebrex® at the time of
8 the occurrence of the injuries alleged by Plaintiff was legally adequate for its approved usages.

9 **Fifteenth Defense**

10 15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the
11 Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable
12 standard of care.

13 **Sixteenth Defense**

14 16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of
15 the product Celebrex® after the product left the control of Defendant and any liability of
16 Defendant is therefore barred.

17 **Seventeenth Defense**

18 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
19 Defendant.

20 **Eighteenth Defense**

21 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
22 conditions unrelated to Celebrex®.

23 **Nineteenth Defense**

24 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,
25 the doctrine of assumption of the risk bars or diminishes any recovery.

26 **Twentieth Defense**

27 20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are
28 preempted in accordance with the Supremacy Clause of the United States Constitution and by the

1 Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

2 **Twenty-first Defense**

3 21. Plaintiff's claims are barred in whole or in part under the applicable state law because the
4 subject pharmaceutical product at issue was subject to and received pre-market approval by the
5 Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

6 **Twenty-second Defense**

7 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
8 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
9 and Plaintiff's causes of action are preempted.

10 **Twenty-third Defense**

11 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
12 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
13 issue under applicable federal laws, regulations, and rules.

14 **Twenty-fourth Defense**

15 24. Plaintiff's claims are barred in whole or in part because there is no private right of action
16 concerning matters regulated by the Food and Drug Administration under applicable federal
17 laws, regulations, and rules.

18 **Twenty-fifth Defense**

19 25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate
20 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of
21 Comment j to § 402A of the Restatement (Second) of Torts.

22 **Twenty-sixth Defense**

23 26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because
24 Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement
25 (Second) of Torts § 402A, Comment k.

26 **Twenty-seventh Defense**

27 27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical
28 product at issue "provides net benefits for a class of patients" within the meaning of Comment f

1 to § 6 of the Restatement (Third) of Torts: Products Liability.

2 **Twenty-eighth Defense**

3 28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
4 Products Liability.

5 **Twenty-ninth Defense**

6 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts
7 sufficient under the law to justify an award of punitive damages.

8 **Thirtieth Defense**

9 30. Defendant affirmatively avers that the imposition of punitive damages in this case would
10 violate Defendant's rights to procedural due process under both the Fourteenth Amendment of
11 the United States Constitution and the Constitutions of the States of Maryland and California,
12 and would additionally violate Defendant's rights to substantive due process under the
13 Fourteenth Amendment of the United States Constitution.

14 **Thirty-first Defense**

15 31. Plaintiff's claims for punitive damages are barred, in whole or in part, by State of
16 Maryland law and by the Fifth and Fourteenth Amendments to the United States Constitution.

17 **Thirty-second Defense**

18 32. The imposition of punitive damages in this case would violate the First Amendment to
19 the United States Constitution.

20 **Thirty-third Defense**

21 33. Plaintiff's punitive damage claims are preempted by federal law.

22 **Thirty-fourth Defense**

23 34. In the event that reliance was placed upon Defendant's nonconformance to an express
24 representation, this action is barred as there was no reliance upon representations, if any, of
25 Defendant.

26 **Thirty-fifth Defense**

27 35. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance to
28 any express representation.

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Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Maryland and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient

1 standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy
2 Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*,
3 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993);
4 *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v.*
5 *Campbell*, 538 U.S. 408 (2003).

6 **Thirty-ninth Defense**

7 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
8 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
9 instructions with respect to the product's use in the package insert and other literature, and
10 conformed to the generally recognized, reasonably available, and reliable state of the knowledge
11 at the time the product was marketed.

12 **Fortieth Defense**

13 40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested,
14 manufactured, and labeled in accordance with the state-of-the-art industry standards existing at
15 the time of the sale.

16 **Forty-first Defense**

17 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
18 and belief, such injuries and losses were caused by the actions of persons not having real or
19 apparent authority to take said actions on behalf of Defendant and over whom Defendant had no
20 control and for whom Defendant may not be held accountable.

21 **Forty-second Defense**

22 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
23 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
24 intended, and was distributed with adequate and sufficient warnings.

25 **Forty-third Defense**

26 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
27 waiver, and/or estoppel.

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Forty-fourth Defense

2 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-
3 existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses,
4 subsequent medical conditions, or natural courses of conditions of Plaintiff, and were
5 independent of or far removed from Defendant's conduct.

Forty-fifth Defense

7 45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
8 did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

10 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did
11 not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

13 47. The claims asserted in the Complaint are barred, in whole or in part, because the
14 manufacturing, labeling, packaging, and any advertising of the product complied with the
15 applicable codes, standards, and regulations established, adopted, promulgated or approved by
16 any applicable regulatory body, including but not limited to the United States, any state, and any
17 agency thereof.

Forty-eighth Defense

19 48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the
20 product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

22 49. The claims asserted in the Complaint are barred because the utility of Celebrex®
23 outweighed its risks.

Fiftieth Defense

25 | 50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral
26 | sources.

Fifty-first Defense

28 51. Defendant's liability, if any, can only be determined after the percentages of

1 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
 2 any, are determined. Defendant seeks an adjudication of the percentage of fault of Plaintiff and
 3 each and every other person whose fault could have contributed to the alleged injuries and
 4 damages, if any, of Plaintiff.

5 **Fifty-second Defense**

6 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
 7 common law gives deference to discretionary actions by the United States Food and Drug
 8 Administration under the Federal Food, Drug, and Cosmetic Act.

9 **Fifty-third Defense**

10 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
 11 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
 12 ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and Plaintiff's
 13 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
 14 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and
 15 with the specific determinations by FDA specifying the language that should be used in the
 16 labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the
 17 Supremacy Clause of the United States Constitution, Art. VI, cl. 2, and the laws of the United
 18 States.

19 **Fifty-fourth Defense**

20 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
 21 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

22 **Fifty-fifth Defense**

23 55. Defendant states on information and belief that the Complaint and each purported cause
 24 of action contained therein is barred by the statutes of limitations contained in California Code
 25 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as
 26 may apply.

27 **Fifty-sixth Defense**

28 56. Defendant states on information and belief that any injuries, losses, or damages suffered

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1 by Plaintiff was proximately caused, in whole or in part, by the negligence or other actionable
 2 conduct of persons or entities other than Defendant. Therefore, Plaintiff's recovery against
 3 Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

4 **Fifty-seventh Defense**

5 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
 6 Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil
 7 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
 8 damages is also barred under California Civil Code § 3294(b).

9 **Fifty-eighth Defense**

10 58. Defendant reserves the right to supplement its assertion of defenses as it continues with
 11 its factual investigation of Plaintiff's claims.

12 **V.**

13 **JURY DEMAND**

14 Defendant hereby demands a trial by jury of all the facts and issue in this case pursuant to
 15 Federal Rule of Civil Procedure 38(b).

16 **VI.**

17 **PRAYER**

18 WHEREFORE, Defendant prays for judgment as follows:

- 19 1. That Plaintiff takes nothing from Defendant by reason of the Complaint;
- 20 2. That the Complaint be dismissed;
- 21 3. That Defendant be awarded its costs for this lawsuit;
- 22 4. That the trier of fact determine what percentage of the combined fault or other liability of
 all persons whose fault or other liability proximately caused Plaintiff's alleged injuries,
 losses or damages is attributable to each person;
- 23 5. That any judgment for damages against Defendant in favor of Plaintiff be no greater than
 an amount which equals Plaintiff's proportionate share, if any, of the total fault or other
 liability which proximately caused Plaintiff's injuries and damages; and
- 24 6. That Defendant has such other and further relief as the Court deems appropriate.

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March 7, 2008

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March 7, 2008

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1 **JURY DEMAND**

2 Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this
3 case pursuant to 38(b) of the Federal Rules of Civil Procedure.

4 March 7, 2008

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14 March 7, 2008

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